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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,613	03/12/2007	Masatoshi Tohata	289779US0PCT	3580
22850 7590 01/07/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
POPA, ILEANA				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
01/07/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
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### Office Action Summary

**Application No.**

10/578,613

**Applicant(s)**

TOHATA ET AL.

**Examiner**

ILEANA POPA

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GA-6)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date See Continuation Sheet

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/17/2008;08/01/2006;05/08/2006.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of *rocR* as the species *Bacillus* gene in the reply filed on 10/29/2009 is acknowledged. The traversal is on the ground(s) that, for restriction to be proper there must be a patentable difference between the species as claimed. MPEP § 808.01(a). The Office has not provided any reasons or examples to support a conclusion that the species are indeed patentably distinct. Accordingly, Applicants submit that the restriction is improper, and Applicants' election of species is for examination purposes only. Applicants request that the election requirement be withdrawn. This is not found persuasive because MPEP § 808.01(a) clearly states that, when there is no disclosure of a relationship between species, they are independent inventions. The Office clearly indicated that the listed gene type do not share a common structure, property or activity, i.e., there is no relationship between the claimed species (see the restrictions requirement mailed on 10/01/2009. The requirement is still deemed proper and is therefore made FINAL.

However, since a search for the elected species yielded results relevant for the species of *slr* and *sigL*, these species are hereby rejoined.

1-7 are pending and under examination.

***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 5, last paragraph). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Priority***

3. Acknowledged is made of Applicant submission of a certified foreign priority paper. It is noted, however, that an English translation of the foreign priority paper has not been provided.

***Claim Objections***

4. Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari et al. (WO 03/083125, published on 10/9/2003, Applicant's IDS).

Ferrari et al. teach a method of producing a secreted protein by using a recombinant *Bacillus subtilis*, wherein the recombinant *Bacillus subtilis* comprises a deletion in the *slr* gene and wherein the recombinant *Bacillus subtilis* further comprises gene encoding a heterologous protein, i.e., the gene comprises a transcription initiation region (claims 1-3 and 7) (p. 1, line 33 to p.2, line 35, p. 3, lines 3-7, p. 36, lines 21-36). The gene encoding a heterologous protein further comprises a translation initiation region and a secretion signal region (claims 3 and 4) (p. 23, lines 24-30, p. 36, lines 3-7). Therefore, Ferrari et al. teach all claim limitations and anticipate the claimed invention.

### **Claim Rejections - 35 USC § 103**

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari et al., in view of both Gardan et al. (Mol. Microbiol., 1997, 24: 825-837) and Hakamada et al. (Biosci. Biotechnol. Biochem., 2000, 64: 2281-2289).

The teachings of Ferrari et al. are applied as above for claims 1-4 and 7. Ferrari et al. do not teach deleting *rocR* or *sigL* (claim 1). However, doing such is suggested by the prior art. For example, Ferrari et al. teach that their method could also employ a recombinant *Bacillus subtilis* comprising a deletion in the *rocA*, *rocD* or *rocF* genes (p.

2, lines 24-29). Gardan et al. teach that *rocR* or *sigL* are transcriptional activators of the *rocA*, *rocD* or *rocF* genes (Abstract, p. 825, column 2, first full paragraph). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the *Bacillus subtilis* of Ferrari et al. by deleting *rocR* or *sigL* to achieve the predictable result of inactivating the *rocA*, *rocD* or *rocF* genes and obtain a microorganism suitable for protein production.

Ferrari et al. and Gardan et al. do not specifically teach using the cellulose transcription initiation, translation initiation and secretion signal regions as set forth by SEQ ID NO: 1 (claims 5 and 6). However, SEQ ID NO: 1 was known in the prior art (see Hakamda et al., p. 2283, column 2, p. 2284, Fig. 1; see also the enclosed sequence alignment). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the *Bacillus subtilis* of Ferrari et al. by replacing their transcription initiation, translation initiation and secretion signal regions with the cellulose transcription initiation, translation initiation and secretion signal regions to achieve the predictable result of obtaining a microorganism suitable for the production of secreted proteins.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

9. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/  
Primary Examiner, Art Unit 1633



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